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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,896	06/11/2001	J. Antoni Rafalski	BB-1313	2782

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E I DU PONT DE NEMOURS AND COMPANY
LEGAL PATENT RECORDS CENTER
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WILMINGTON, DE 19805

EXAMINER	
BUI, PHUONG T	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/857,896	Applicant(s) Cahoon et al.
	Examiner Phuong Bui	Art Unit 1638

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Jul 21, 2003*

2a) [X] This action is **FINAL**. 2b) [ ] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *24, 26-28, 31-35, and 37-40* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *24, 26-28, 31-35, and 37-40* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [X] The drawing(s) filed on *Jul 21, 2003* is/are a) [X] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examine

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____ .
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [X] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [ ] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s). *7/21/03*
4) [ ] Interview Summary (PTO-413) Paper No(s). _ _ _
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other:

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's Amendment filed July 21, 2003. Claims 24, 26-28, 31-35 and 37-40 are pending and are examined in the instant application. This action is made FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

3. An initialed and dated copy of Applicant's supplemental IDS form 1449, filed July 21, 2003 is attached to the instant Office action.

Claim Rejections - 35 USC § 112, second paragraph

4. Claims 24, 26-28, 31-35 and 37-40 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "a disease resistance mediating Mlo polypeptide" as amended is unclear because "mediating" is not defined. It is unclear whether function is intended by the recitation of "disease resistance mediating Mlo polypeptide". Said recitation could also mean that the nucleotide sequence is obtained from a sequence encoding an Mlo polypeptide, absent functional activity. Assuming arguendo that "disease resistance mediating" implies function, it is unclear whether "mediating" means expression of the polypeptide increases disease resistance, renders the plant disease susceptible, or whether the polypeptide acts on or in concert with other proteins to increase or decreases disease resistance in

a plant when expressed. Without knowing how the Mlo polypeptide mediates disease resistance, one skilled in the art would not be able to determine sequences having 90% to 95% sequence identity with SEQ ID NO:32 and having Mlo polypeptide disease resistance mediating activity. Again, the purpose of 35 USC 112, second paragraph is to allow the public to determine exactly what the boundaries of the claimed invention are. In the instant application, the claims are drawn to sequences encoding polypeptides having 90-95% sequence identity to SEQ ID NO:32. While the activity of SEQ ID NO:32 may be inherent in a complete protein, sequences encoding polypeptides having *x*% sequence identity to SEQ ID NO:32, and either 1) is obtained from an Mlo polypeptide or 2) having "disease resistance mediating Mlo polypeptide" activity cannot be reasonably apprised by one skilled in the art for the reasons set forth above. In the instant application, "disease resistance mediating Mlo polypeptide" does not imply a function, and while "Mlo" may be terms of the art, one skilled in the art would not be reasonably apprised of the metes and bounds of what nucleotide sequences are encompassed by "encoding a disease resistance mediating Mlo polypeptide".

Claim 40 fails to further limit claim 24, as claim 40 recites "part of" and does not require a sequence having 90% sequence identity with SEQ ID NO:32 at the amino acid level. Clarification is required.

Claim Rejections - 35 USC § 101 Utility

5. Claims 24, 26-28, 31-35 and 37-40 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility for reasons of record. Applicant traverses, stating primarily that partial or complete

inactivation of Mlo results in the priming of the disease-resistance response, that over-expressing chalcone synthase resulted in cosuppression of itself and the normal flower gene, and that repression may occur where the introduced sequence contains no coding sequence *per se* but only intron or untranslated sequences substantially homologous to sequences present in the primary transcript of the endogenous sequence. Applicant's traversals have been considered and are unpersuasive for the following reasons. First of all, the claims are drawn to nucleotide sequences having 90% sequence identity at the amino acid level. Neither the state of the prior art nor Applicant's disclosure teaches partial or complete inactivation of the Mlo gene using degenerant DNAs. While partial sense or antisense DNA sequences which hybridize to the complementary strand of a gene have been used to inactivate a gene, it is not known how degenerant DNAs can be used for this purpose (see previous Office action). Secondly, the language recited in the claims, specifically "a disease resistance mediating Mlo polypeptide", implies that the claimed sequences are intended to encode proteins or polypeptides capable of mediating disease resistance. Thus, Applicant's arguments are not commensurate in scope with the claims because the claims do not encompass introns or untranslated sequences as argued. Thirdly, it is unclear how teachings of Jorgenson's overexpression of chalcone synthase which muted both itself and the normal flower gene correlates to the Mlo polypeptide of the instant application which purportedly mediates disease resistance. While co-suppression phenomenon has been observed for some proteins, there is no evidence that Mlo polypeptide has the same or similar mode of action as Jorgenson's chalcone synthase, i.e., that overexpression of Mlo would increase disease resistance. Moreover, the same argument can be made to the contrary: that overexpressing of Mlo would ablate any

disease resistance the plant initially had. Fourthly, it is noted that Applicant is arguing that both over-expressing and inhibiting Mlo expression would somehow "mediate" disease resistance. Applicant does not disclose as such in the specification but relies on additional references to provide essential materials necessary to practice the claimed invention. Since it is unclear how Mlo "mediates" disease resistance, it would appear that further research is required to identify or reasonably confirm a "real world" context of use. Accordingly, the claimed invention lacks utility under current utility guidelines.

Claims 24, 26-28, 31-35 and 37-40 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Applicant's traversals have been addressed in the 35 U.S.C. 101 rejection above.

Additionally, newly added claim 40 is not enabled because the method is directed to producing plants having reduced Mlo polypeptide. However, the steps set forth encompass expressing a recombinant Mlo polypeptide. Since expressing any amount of the recombinant Mlo polypeptide would increase rather than reduce the recombinant Mlo polypeptide in a plant, the steps set forth would have the opposite result from the method as directed. If Applicant intends to rely on the co-suppression phenomenon discussed in the U.S.C. 101 rejection above, Applicant should note that while the total level of Mlo polypeptide in a transformed plant may decrease, the expression of the recombinant Mlo polypeptide cannot. Co-suppression has been discussed in the U.S.C. 101 rejection above.

Claim Rejections - 35 USC § 112, first paragraph

6. Claims 24, 26, 31-35 and 37-40 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant traverses and provides evidentiary showing of conserved domains of Mlo family members. Applicant's traversal is unpersuasive because while conserved domains may help identify Applicant's claimed sequence and may place Applicant's sequence in a protein family, it does not allow one skilled in the art to reliably predict the structure of other sequences from other species, mutants or variants. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing under current written description guidelines.

Remarks

7. No claim is allowed. The claims are free of the prior art.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (703) 305-1996.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui
Primary Examiner
Group Art Unit 1638
October 19, 2003

PHUONG T. BUI
PRIMARY EXAMINER
10/20/03